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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/687,529 | 10/16/2003 | Peter Abel | 33637/US | 5228 |
| 7590 | 12/28/2005 | | | |
| | | | EXAMINER | |
| | | | FERNANDEZ, SUSAN EMILY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/687,529 | ABEL ET AL. | |
| | Examiner Susan E. Fernandez | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 October 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 16-20,24,25,27-30 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 16-20,24,25,27-30 and 32-37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

The amendment and declaration filed October 20, 2005, have been received and entered.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 16-20, 24, 25, 27-30, and 32-37 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-30, 33, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is rendered indefinite by the phrase “the enzyme layer,” which lacks antecedent basis. Parent claim 16 does not recite an “enzyme layer”, and instead recites an “enzyme region”. Thus, claims 28-30 are rejected under 35 U.S.C. 112, second paragraph.

Claim 33 is rendered indefinite by the phrase “the diffusion channel,” which lacks antecedent basis as parent claim 16 does not recite any diffusion channels. Furthermore, it is not clear what feature of the cross-section of the diffusion channel is used in the ratio. Specifically, it is not clear whether a parameter such as the area, circumference, diameter, or radius of the cross-section is used in the ratio that is determined. Therefore, the rejection of claim 33 under 35 U.S.C. 112, second paragraph is maintained.

Claim 35 is indefinite because the phrase “...said porous layer providing an increased cross-section of the channel”. The phrase is confusing and it is unclear how the porous layer of the surface provides an increased cross-section of the channel.

Additionally, claim 35 is rendered indefinite by the phrase “outer concentration gradients.” First, it is not clear which substance’s concentration is included in the “outer concentration gradients”. Additionally, it is unclear what is defined by “outer”, which is included in the phrases “outer concentration gradients” and “outer deposits”. Is it referring to the region outside the channel entrances? Finally, “diffusion flow” renders claim 35 indefinite because it is not clear which “diffusion flow” is encompassed. Thus, the rejection of claim 35 under 35 U.S.C. 112, second paragraph is maintained.

Claim Rejections - 35 USC § 102

Claims 16-20, 24, 25, 27, 32-33, and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Janssen et al. (EP 539625).

Janssen et al. discloses a sensor diagrammed on Figure 1. See abstract and column 3, line 34 through column 4, line 11. On Figure 1, the enzyme region is (7), comprising of glucose oxidase in a hydrogel. By definition, a hydrogel contains water. The enzyme region is covered on one side by (8), a material impermeable to the analyte, glucose. Enzyme region (7) is connected to the surface of the sensor by (10), an opening or hole which serves as a channel which leads through impermeable material (8). This channel contains water since its entrance is covered by (9), a water-permeable membrane. Thus water is allowed through (10). Moreover,

the portion of (9) above (10) serves as a section of the channel. Therefore, the length of the channel exceeds the thickness of membrane (8).

(9) is defined as being impermeable to high molecular weight components, thus it is impermeable to proteins. Furthermore, (9) is porous because it allows the passage of water and oxygen gas. Therefore, the channel is filled adjacent to the surface of the sensor with a porous substance impermeable to proteins. In other words, the region of (9) above (10) serves as a protein-impermeable, hydrophilic layer that the channel passes into on the surface of the sensor.

(12) of Figure 1 demonstrates the diffusion path of glucose. Due to the fact that (8) is impermeable to glucose, the channel forms the only route for transport of glucose to glucose oxidase.

Additionally, there is one portion (or “side”) of the enzyme region covered by the analyte-impermeable, oxygen-permeable membrane (9) where there is no “analyte window” because (10) is not present.

A holding of anticipation is clearly required.

Applicant's arguments have been fully considered but they are not persuasive. Specifically, applicant indicates that Janssen fails to teach the invention because Janssen teaches “a membrane impermeable to glucose (8), having an opening or hole (10) rendering said membrane locally permeable for glucose”. However, as discussed above, (10) and the portion of (9) directly above (10) constitutes the channel recited in claim 16 under examination. (10) is not considered an analyte window, thus, the enzyme region (7) of Janssen et al. is indeed coupled on at least one side to an analyte-impermeable, oxygen-permeable membrane (8) having no analyte window. Therefore, the rejections under Janssen et al. are properly maintained.

Claim Rejections - 35 USC § 103

Claims 16-20, 24, 25, 27-30, and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janssen et al. in view of Clark, Jr. (U.S. Pat. 4,680,268).

As discussed above, Janssen et al. anticipates claims 16-20, 24, 25, 27, 32-33, and 35-36. However, Janssen et al. does not expressly disclose an inner gas space of the sensor that borders the glucose oxidase layer. Furthermore, it does not disclose that the length of the channel in the sensor is between 0.1 mm and 1 mm.

Clark, Jr. discloses an implantable sensor as described in column 6, lines 14-68, and shown on Figure 1. The sensor includes an enzyme layer (7) which can be glucose oxidase, thus requiring glucose as the analyte (column 10, lines 50-54). The enzyme layer (7) borders an inner gas space (12). The enzyme layer (7) is separated from the inner gas space (12) by a gas-permeable membrane (6a) (column 6, lines 16-20). Membrane (6a) is porous and hydrophilic as it allows passage of gas, including water vapor. Furthermore, inner gas space (12) is in a chamber (6) constructed of gas permeable material allowing for the extraction of oxygen from the sensor's exterior (column 6, lines 53-54, and column 7, lines 29-31). Thus the environment surrounding the chamber serves as an "oxygen reservoir".

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have included an inner gas space in the Janssen sensor which borders the enzyme layer, wherein the enzyme layer and the gas space are separated by an oxygen-permeable membrane. This inner gas space would have been in communication with an oxygen

reservoir. Additionally, the selection of a suitable channel length would have been a routine matter of optimizing a result-effective parameter at the time of applicant's invention.

One of ordinary skill in the art would have been motivated to do this because Clark, Jr. indicates that their invention is "predicated in part upon the discovery that problems heretofore associated with enzyme sensors can be overcome by providing a structure for an ample and/or steady supply of oxygen for enzymatic reaction at the sensor surface" (column 3, lines 43-47). A holding of obviousness is therefore clearly required.

Applicant's arguments have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant notes that Clark teaches "membrane 10 is permeable to small molecules, such as glucose and lactate." However, the Clark reference is used to provide motivation for including an inner gas space in the Janssen sensor. As discussed above, Janssen alone teaches many of the claims under examination, and indeed teaches an analyte-impermeable, oxygen permeable layer without an analyte window. Therefore, the rejections over Janssen et al. in view of Clark, Jr. are properly maintained.

Claims 16-20, 24, 25, 27, 32, 33, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janssen et al. in view of von Woedtke et al. (Sensors and Actuators B, 1997, B42(3): 151-156).

As discussed above, Janssen et al. anticipates claims 16-20, 24, 25, 27, 32-33, and 35-36.

However, Janssen et al. does not expressly disclose that the channel in the sensor leads through a water-impermeable material.

von Woedtke et al. discloses a sensor comprising of a layer of glucose oxidase covered by a membrane with an analyte door. See Figure 2 on page 152. The membrane is a hydrophobic, gas-permeable membrane, thus it is impermeable to water.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have ensured that membrane (8) of the Janssen invention is impermeable to water in addition to glucose

One of ordinary skill in the art would have been motivated to do this because water participates in the catalytic reaction involving glucose oxidase and its substrate, glucose. Furthermore, concentration gradients of oxygen are affected by the fluid flow of water into the enzyme layer. According to Janssen et al., "...the relation between the glucose content in the fluid to be measured and the detection current obtained in the detection electrode is very sensitive to...the concentration or concentration gradient of the oxygen in the sensor itself" (column 2, lines 15-22). Thus, in order to have obtained optimal sensor sensitivity, one would have been motivated to have made modifications that would have eliminated or minimized factors that affect oxygen concentration gradient. A holding of obviousness is therefore clearly required.

Applicant's arguments have been fully considered but they are not persuasive. As discussed above, Janssen et al. discloses each element of the independent claim. Therefore, rejections over Janssen et al. in combination with other references are properly maintained.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan E. Fernandez
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